

REMARKS

These remarks are in response to the Office Action mailed December 12, 2007. Claim 48 has been amended so as to make it dependent on independent claim 30 rather than cancelled claim 47. No new matter is believed to have been introduced by the foregoing amendments.

I. REJECTION UNDER 35 U.S.C. §112

Claim 48 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite because it was dependent on cancelled claim 23. Claim 48 has been amended so as to be dependent on independent claim 30, thus rendering this rejection moot.

The correct format of claim 39, 48 and 54 before the present amendment is set forth in the paper filed April 20, 2007, wherein claim 48 is dependent on claim 47 and "two or more cured polymer scaffolds" is recited instead of "two dimensional structures."

II. REJECTION UNDER 35 U.S.C. §103 OVER MA IN VIEW OF MAHMOOD

Claims 30, 34-38, 45-46, 49 and 64 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ma (U.S. Patent No. 6,872,387) in view of Mahmood *et al.* (EP 1,027,897). Applicants respectfully traverse this rejection.

According to the Official Action, ". . . Ma appears not to teach an assembly of two or more polymer scaffolds to provide a layered polymer scaffold" whereas "Mahmood *et al.* teach this aspect." The Office Action further asserts that "[i]t would have been obvious to one of ordinary skill in the art to incorporate this teaching of Mahmood *et al.* into the scaffold structure of Ma in order to produce engineered tissue."

The position set forth in the Official Action is deficient, at least, in that it provides no explanation whatsoever as to **why** it would have been obvious to incorporate the teaching of Mahmood *et al.* into the scaffold structure of Ma. With regard to the contents of a 35 U.S.C. §103 rejection, MPEP §706.02(j) clearly states that "the examiner should set forth in the Office action: . . . (D) an explanation as to why the claimed invention would have been obvious to one of ordinary skill in the art

at the time the invention was made." Without this explanation, the instant §103 rejection does not satisfy even the minimum criteria which the U.S. Patent Office has indicated are necessary to support a proper *prima facie* case of obviousness. Accordingly, the rejection should be withdrawn.

It is not surprising that the examiner could not provide an explanation as to why one would have combined the teachings of Ma and Mahmood *et al.* as the disclosures in those documents are completely unrelated. Ma relates to the use of ionically crosslinked alginate gels as scaffolds for in vitro tissue engineering applications. Mahmood *et al.*, on the other hand, describes the use of a porous matrix formed of a copolymer of a polyalkylene glycol and an aromatic polyester as a scaffold for tissue engineering cartilage. Thus, Ma and Mahmood *et al.* employ completely different substances for tissue engineering applications and there is no apparent reason why one would combine these different approaches.

Furthermore, at most Mahmood *et al.* describe combining only a polymer with a non-polymer (i.e., polymer and ceramic). In contrast, the present application is directed to layering two polymeric materials (e.g., the same material over and over again). Mahmood *et al.* provide hybrid material comprising a non-polymeric material providing different properties between the two constituents - a completely different 'why'. Applicants' invention changes the architecture not mechanical properties, a different problem and result that is neither suggested nor taught by Mahmood *et al.* It would not have been obvious that one can, in fact, form multilayers of the same material. For example, the fusion of laminated structures was long thought to require an additional interfacial layer, e.g., a glue or a solvent to 'redissolve' the interface-unreacted groups that could then cross-link across the interface. In fact, complex structures.

It is important to note that the reference fail to teach or suggest each and every element of Applicants' independent and dependent claims. For example, the subject matter of claims 31, 48, 50-53 and 60-64 are not taught or suggested in the cited references either alone or when combined.

For at least the reasons set forth above, withdrawal of the §103 rejection over Ma and Mahmood *et al.* is requested.

III. REJECTION UNDER 35 U.S.C. §103 OVER MAHMOOD

Claims 31, 50-53 and 60-63 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Mahmood *et al.* (EP 1,027,897). Applicants respectfully traverse this rejection.

Applicants respectfully submit that the Office Action indicates at page 2, Section 3, that the combination of Ma and Mahmood *et al.* do not render claims 31, 48, and 50-53 obvious. Accordingly, Applicants submit that the secondary reference of Mahmood *et al.* alone cannot render claims 31, 48 and 50-53 obvious based upon the foregoing rejection. The Applicants, thus, respectfully request withdrawal of the rejection of at least claims 31, 48 and 50-53.

As discussed above, Mahmood *et al.* describes the use of a porous matrix formed of a copolymer of a polyalkylene glycol and an aromatic polyester as a scaffold for tissue engineering cartilage. Independent claim 31 recites "[a] microfabricated polymer scaffold comprising a membrane comprised of a surface with varying topology." As stated by the specification at paragraph [0029], "[v]arying topology refers to surfaces that have variations in height." Mahmood *et al.* is deficient, at least, in that it does not describe a microfabricated polymer scaffold comprising a membrane comprised of a surface with varying topology.

Recognizing the deficiencies of Mahmood *et al.*, the Official Action tries to rationalize the position set forth therein by stating that "[i]t is submitted that the structure of Mahmood *et al.* inherently has a varied or varying topology when viewed at a microscopic level." Thus, the Patent Office has taken a position of relying on inherency to justify an obviousness rejection. Such an approach, however is not permissible, as explained by the Federal Circuit in *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). There, the court summed up this area of the law in a series of quotations, as follows:

"The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency.]" *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)(citations omitted)(emphasis added). "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is

unknown." *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966). Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. See *In re Newell*, 891 F.2d 899, 901, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989). (28 USPQ2d at page 1957)

From the foregoing it should be apparent that inherency cannot be used to justify a rejection based on obviousness. Therefore, when the proper standards for obviousness are considered, one reaches the inevitable conclusion that the claimed subject matter would not have been obvious over Mahmood *et al.* Withdrawal of the §103 rejection based on Mahmood *et al.* is therefore requested.

Applicants believe the foregoing comments and amendments overcome the rejections presented in the Office Action. Accordingly, Applicants respectfully request withdrawal of the rejections.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY LLP

Date: April 14, 2008

By: /Joseph R. Baker, Jr./
Joseph R. Baker, Jr.
Registration No. 40,900

P.O. Box 1404
Alexandria, VA 22313-1404
(858) 509 7300